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EXAMINER

ROGERS, JAMES WILLIAM

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JESSICA R. DESNOYER, SYED F.A. HOSSAINY,
STEPHEN D. PACETTI, and YIWEN TANG

Appeal 2009-003670
Application 10/750,139
Technology Center 1600

Decided: May 6, 2010

Before ERIC GRIMES, DONALD E. ADAMS, and DEMETRA J. MILLS,
Administrative Patent Judges.

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1-58 the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties (claims 1-11); a coating composition (claims 12-22, 55 and 56); an implantable device (claims 23-44, 57, and 58); and a method of treating a disorder in a human being by implanting a stent in the human being (claims 45-54).

Claims 1, 3, and 4 are illustrative:

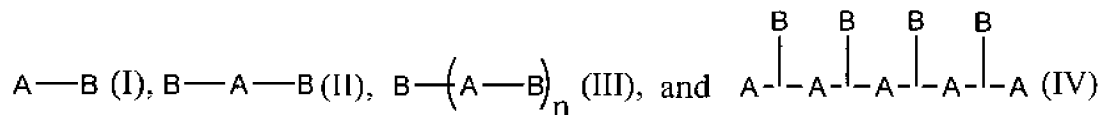
1. A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

3. The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. The method of claim 3 wherein A is selected from the group consisting of poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-lactide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-

glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

The Examiner relies on the following evidence:

Roby et al.	WO 98/32398	Jul. 30, 1998
Pinchuk et al.	US 2002/0107330 A1	Aug. 8, 2002
Pacetti	WO 03/022323 A1	Mar. 20, 2003

The rejections presented by the Examiner follow:

1. Claims 1-3 and 5-58 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Pacetti and Roby.
2. Claim 4 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Roby and Pinchuk.

We affirm.

PRINCIPLES OF LAW

“[T]he [E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). It is proper to “take account of the

inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). In sum, the “suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006).

“Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). Where a rejection is based on a combination of references, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425.

“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *KSR*, 550 U.S. at 419.

Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The combination of Pacetti and Roby:

ISSUE

Does the evidence of record support the Examiner's conclusion that Appellants' claimed invention would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made in view of the combination of Pacetti and Roby?

FINDINGS OF FACT

FF 1. "Pacetti discloses a coating for reducing the rate [of] release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent" (Ans. 3; *see also* App. Br. 9 and Reply Br. 5).

FF 2. Pacetti's polymers include polyurethanes with polydimethylsiloxane soft segments and poly(vinylidene fluoride-co-methacrylic acid) (*id.*).

FF 3. The Examiner finds that "polymers including polyurethanes with [] polydimethylsiloxane soft segments and poly(vinylidene fluoride-co-methacrylic acid)" are low surface energy, surface blooming polymers within the scope of Appellants' claimed invention (Ans. 9).

FF 4. "Pacetti does not disclose the use of PEA in combination with . . . [a] low surface energy polymer or low surface energy, surface blooming polymer[], to produce a coating containing a therapeutic for a stent" (Ans. 4).

FF 5. Roby teaches that compositions comprising polyesteramides (PEAs) can be used as an absorbable coating for surgical devices (Roby 6: 34 - 7: 1; Ans. 4).

FF 6. Roby teaches that the polyesteramide compositions may include therapeutic agents (Ans. 4).

FF 7. Roby teaches that “[t]he polyesteramides can be used alone, blended with other absorbable compositions, or in combination with non-absorbable components” (Roby 6: 27-29; Ans. 6).

FF 8. “Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties” (Ans. 4).

FF 9. “Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition” (Ans. 3).

ANALYSIS

Appellants provide separate arguments the following groups of claims: (I) claims 1-3, 5-7, and 53; (II) claims 8-11 and 54; (III) claims 12-18 and 55; (IV) claims 19-22 and 56; (V) claims 23-29, 34-38, 41, 42, 45-49, 51, and 57; and (VI) claims 30-33, 39, 40, 43, 44, 50, 52, and 58. Claims 1, 8, 12, 19, 23, 30 are representative. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 1:

Appellants agree that Pacetti teaches a coating that includes a polymer capable of maintaining its crystalline lattice structure (App. Br. 9; FF 1) and that these polymers can be polyurethanes with polydimethylsiloxane soft segments or poly(vinylidene fluoride-co-methacrylic acid) (Reply Br. 5; FF 2-3). Nevertheless, Appellants contend that Pacetti does not “describe a coating that includes a PEA”; therefore, Pacetti does not “describe or teach forming a coating comprising [both] . . . a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone” (App. Br. 9).

Similarly, while Appellants recognize that Roby teaches compositions comprising PEA; Appellants contend that Roby does not teach “a composition that comprises [both] a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone” (App. Br. 9-10).

In essence, Appellants contentions are directed to what each reference teaches in isolation rather than what the combination of Pacetti and Roby, taken together, teach a person of ordinary skill in this art. The test for obviousness, however, is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425; *see also* Ans. 9. Accordingly, we are not persuaded by Appellants’ contention that each reference, taken alone, fails to suggest Appellants’ claimed invention.

We are also not persuaded by Appellants’ contention that neither Pacetti nor Roby “recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming

polymer” (App. Br. 10; *see also* Reply Br. 5 (The bioabsorbability and good mechanical properties of a PEA polymer disclosed in Roby and control of release of drug by the crystalline polymers disclosed in Pacetti “are not germane to the issues associated [with] the coating of a PEA polymer as Applicants recognized”)). “In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *KSR*, 550 U.S. at 419.

On this record, both Pacetti and Roby teach coatings compositions for medical devices (FF 1 and 5). Both Pacetti and Roby teach that the coatings may comprise therapeutic agents (FF 1 and 6). Roby teaches that the PEAs “can be used alone, blended with other absorbable compositions, or in combination with non-absorbable components” (FF 7). Therefore, Roby suggests a composition comprising (1) PEA and (2) the PEA miscible, low surface energy, surface blooming polymers taught by Pacetti (i.e. polydimethylsiloxane soft segments or poly(vinylidene fluoride-co-methacrylic acid)). Pacetti teaches that the polymers are capable of maintaining a “crystalline lattice structure while the therapeutic agent is released from the stent” (FF 1). Roby teaches that PEA provides desirable mechanical properties in addition to the ability to be absorbed or resorbed by the body (FF 8). Lastly, Pacetti teaches that the composition can be applied to the medical device (e.g., stent) by “spraying the composition on the device or by immersing the device in the composition” (FF 1 and 9).

In sum, when considered together from the perspective of a person of ordinary skill in this art, the combination of Pacetti and Roby suggests a

method wherein a composition (e.g., a solution or suspension) comprising a PEA and a PEA miscible, low surface energy, surface blooming polymer block or backbone is applied to an implantable device (e.g., a stent) to form a coating. The combination of Pacetti and Roby suggest that such a coating will have desirable mechanical properties and release rates for therapeutic agents incorporated into the coating. Appellants fail to provide persuasive evidence or argument to support a conclusion that the mechanical properties and release rates suggested by the combination of Pacetti and Roby are not enhanced.

Lastly, we are not persuaded by Appellants' contention that the Roby teaches away from a combination with Pacetti because Pacetti's polymers are non-absorbable or biodurable polymers. Roby suggest a composition comprising PEA and absorbable *or non-absorbable components* (FF 7). Therefore, notwithstanding Appellants' contention to the contrary, the disclosure of Roby suggests its combination with Pacetti.

Claim 8:

"Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone" (App. Br. 10; Claim 8).

Appellants contend that

Pacetti [] and Roby fail to teach or suggest the method of forming a coating including a PEA polymer and at least one low surface energy polymer additive comprising a PEA miscible block or PEA miscible backbone. Therefore, claim 8 is non-obvious over Pacetti [] and Roby under 35 U.S.C. § 103(a).

(App. Br. 10.) For the reasons set forth above, we are not persuaded.

Claim 12:

“Claim 12 defines [a] coating composition for coating an implantable device. The composition comprises a . . . [PEA] and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone” (App. Br. 10; Claim 12).

Appellants contend that “Pacetti [] and Roby fail to teach or suggest such a coating composition. Claim 12 is thus non-obvious over Pacetti [] and Roby under 35 U.S.C. [§] 103(a)” (App. Br. 10). For the reasons set forth above, we are not persuaded.

Claim 19:

“Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone” (App. Br. 11; Claim 19).

Appellants contend that “Pacetti [] and Roby fail to teach or suggest such a coating. Therefore, claim 19 is thus non-obvious over Pacetti [] and Roby under 35 U.S.C. [§] 103(a)” (App. Br. 11). For the reasons set forth above, we are not persuaded.

Claim 23:

“Claim 23 defines an implantable device comprising a coating which comprises a . . . [PEA] and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone” (App. Br. 11; Claim 23).

Appellants contend that “Pacetti [] and Roby fail to teach or suggest such an implantable device. Therefore, claim 23 is non-obvious over Pacetti [] and Roby under 35 U.S.C. [§] 103(a)” (App. Br. 11). For the reasons set forth above, we are not persuaded.

Claim 30:

“Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone” (App. Br. 11; Claim 30).

Appellants contend that “[f]or the reasons mentioned above, claim 30 is non-obvious over Pacetti [] and Roby under 35 U.S.C. [§] 103(a)” (App. Br. 11). For the reasons set forth above, we are not persuaded.

CONCLUSION OF LAW

The evidence of record supports the Examiner’s conclusion that Appellants’ claimed invention would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made in view of the combination of Pacetti and Roby.

The rejection of claims 1, 8, 12, 19, 23, and 30 under 35 U.S.C. § 103(a) as unpatentable over the combination of Pacetti and Roby is

affirmed. Claims 2, 3, 5-7, and 53 fall with claim 1. Claims 9-11 and 54 fall with claim 8. Claims 13-18 and 55 fall with claim 12. Claims 20-22 and 56 fall with claim 19. Claims 24-29, 34-38, 41, 42, 45-49, 51, and 57 fall with claim 23. Claims 31-33, 39, 40, 43, 44, 50, 52, and 58 fall with claim 30.

The combination of Roby and Pinchuk:

ISSUE

Does the evidence of record support the Examiner's conclusion that Appellants' claimed invention would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made in view of the combination of Roby and Pinchuk?

FINDINGS OF FACT

FF 10. The Examiner relies on Roby as discussed above (Ans. 6; FF 5-8).

FF 11. "Roby does not disclose the low surface energy polymers as recited in claim 4" (*id.*).

FF 12. Pinchuk "discloses coatings over an intravascular or intervascular medical device comprising a biocompatible polymer" that is loaded with a therapeutic agent (*id.*; Pinchuk, Abstract and 1: ¶¶ [0010]-[0011]).

FF 13. Pinchuk teaches that the biocompatible polymer is

[A]n A-B block copolymer that meets [A]ppellants claimed block copolymer. The blocks could contain monomers of methacrylate (meets poly(methacrylate[])) of [A]ppellants claimed group A within claim 4) and polyolefin monomers that when polymerized will form an alkyl chain (meeting [A]ppellants claimed group B within claim 4). Furthermore . . . Pinhcuck [sic] outlines the use of other copolymers that can

include blocks of polycaprolactone, polyglycolic acid (both meet [A]ppellants claimed group A within claim 4) and siloxane polymers (meets [A]ppellants claimed group B within claim 4).

(Ans. 8.)

ANALYSIS

We are not persuaded by Appellants' contention that each reference, taken alone, fails to suggest Appellants' claimed invention. *In re Keller*, 642 F.2d at 425.

On this record, both Roby and Pinchuk teach coating compositions for medical devices (FF 1 and 12). Both Pinchuk and Roby teach that the coatings may comprise therapeutic agents (*id.*). Roby teaches that the PEAs "can be used alone, blended with other absorbable compositions, or in combination with non-absorbable components" (FF 7). Therefore, Roby suggests a composition comprising (1) PEA and (2) the PEA miscible, low surface energy, surface blooming polymers taught by Pinchuk (i.e. polyolefin monomers that when polymerized will form an alkyl chain) (FF 13). Pinchuk's coating is an A-B block copolymer, wherein the A group is poly(methacrylate) and the B group is an alkyl chain (FF 13).

In sum, when considered together from the perspective of a person of ordinary skill in this art, the combination of Roby and Pinchuk suggests a method wherein a composition comprising a PEA and a PEA miscible, low surface energy, surface blooming polymer block or backbone is applied to an implantable device (e.g., a stent) to form a coating. The combination of Roby and Pinchuk suggest that such a coating will have desirable mechanical properties and release rates for therapeutic agents incorporated

into the coating. Appellants fail to provide persuasive evidence or argument to support a conclusion that the mechanical properties and release rates suggested by the combination of Roby and Pinchuk are not enhanced.

Contrary to Appellants' intimation, the A group of Appellants' claim 4 is not limited to "poly(ester-urea) urethane, poly(ether-urethane), . . . poly(carbonate-urethane), poly(silicone-urethane), or poly(urea-urethane)" (App. Br. 8). Instead, the A group of Appellants' claim 4 includes, *inter alia*, poly(methacrylate) which is taught by Pinchuk (FF 13; *see also* Reply Br. 3 (where Appellants concede that Pinchuk demonstrates that "an AB block copolymer [is] known in the art")). Accordingly, we are not persuaded by Appellants' contention that Pinchuk "does not [teach] . . . an A component" within the scope of Appellants' claim 4 (App. Br. 8).

We are also not persuaded by Appellants' contention that "nothing in Roby and Pinchuk provides motivation for a person of ordinary skill in the art to combine the PEA polymer in Roby and the polymers in Pinchuk so as to make a coating as defined by claim 4" (Reply Br. 3). Roby teaches that the PEAs "can be used alone, blended with other absorbable compositions, or in combination with non-absorbable components" (FF 7). Therefore, Roby suggests its combination with Pinchuk. Notwithstanding Appellants' contention to the contrary (Reply Br. 3), the reason to combine the references does not have to be the same as Appellants'. *KSR*, 550 U.S. at 419.

CONCLUSION OF LAW

The evidence of record support the Examiner's conclusion that Appellants' claimed invention would have been *prima facie* obvious to a

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person of ordinary skill in the art at the time the invention was made in view of the combination of Roby and Pinchuk.

The rejection of claim 4 under 35 U.S.C. § 103(a) as unpatentable over the combination of Roby and Pinchuk is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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